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510(k) SUMMARY
NIDEK GREEN LASER PHOTOCOAGULATOR MODEL MC-300

1. SUBMITTER INFORMATION

A.	Company Name:	Nidek Incorporated
B.	Company Address:	47651 Westinghouse Drive. Fremont, CA 94539-7474
C.	Company Phone: Company Fax:	(510) 353-7722 (510) 226-5750
D.	Contact Person:	Hiro Matsuzaki Manager, Regulatory Affairs Nidek Incorporated
E.	Date Summary Prepared:	September 30, 2004

2. DEVICE IDENTIFICATION

A.	Classification Name:	Ophthalmic Laser, and Powered Surgical Laser Instrument
B.	Trade/Proprietary Name:	Nidek Multi Color Laser Photocoagulator Model MC-300
C.	Device Classification:	Class II (per 21 CFR 886.4390 and 878.4810)
D.	Product Code:	HQF and GEX

3. SUBSTANTIAL EQUIVALENCE

The Nidek Multi Color Laser Photocoagulator Model MC-300 is of comparable type and is substantially equivalent to the following predicate devices:

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Predicate Device	Manufacturer	510(k) No.	Date Cleared
Nidek Laser Photocoagulator Model GYC-1000	Nidek Co. Ltd. Japan	K032085	October 3, 2003
Lumenis Novus Varia Ophthalmic Laser & Delivery Devices	Lumenis, Inc.	K022181	October 1, 2002

The fundamental technical characteristics and device specifications of the Nidek Multi Color Laser Photocoagulator Model MC-300 are the same as those of the predicate devices. The Model MC-300 and the predicate devices are all Diode Laser Pumped Solid State Lasers (DPSSL). The Model MC-300 and the predicate device use a variety of delivery systems, including slit lamps, to deliver the laser beam. The Model MC-300 and the predicate devices are indicated for use in surgical treatment of ocular pathology, including retinal photocoagulation, panretinal photocoagulation, intravitreal endophotocoagulation, iridotomy, iridectomy and trabeculoplasty.

4. DEVICE DESCRIPTION

The Nidek Multi Color Laser Photocoagulator Model MC-300 is a diode pumped solid state laser (DPSSL) ophthalmic photocoagulation system that produces three treatment beams: a 532 nm (green) wavelength, a 561 (yellow) wavelength, and a 659 (red) wavelength. The Model MC-300 uses the same wavelength for the aiming beam as the treatment beams, so that the operator can recognize the selected wavelength by the color of the aiming spot. The Model MC-300 splits the pumped laser beam into the aiming and treatment beams so that they can both be controlled separately. The multi-color laser beam is aligned with the respective aiming laser beam in the optical system inside the unit and gathers them in a fiber optic cable. The laser beam is led to the delivery unit via the fiber-optic cable, shaped into the specified spot size in the

optical system, and emitted to the affected area (the emission areas of both the therapeutic laser beam and the aiming beam are the same).

The Model MC-300 can be used to coagulate the target tissue efficiently and safely, and the system can be applied to transpupillary photocoagulation procedures using a slit-lamp.

A protective filter may be attached to each delivery unit in the observation optical path so that the operator's eye can be protected from the laser beam if it is reflected from a patient's eye or contact lens during laser emission. The Model MC-300 uses the following delivery units for use in a variety of ophthalmic procedures:

- NIDEK Slit-Lamp Delivery Unit
- ZEISS Slit-Lamp Attachable Delivery Unit
- Binocular Indirect Ophthalmoscope Delivery Unit (Keeler All Pupil II Type)

5. INTENDED USE

The Nidek Multi Color Laser Photocoagulator Model MC-300 is indicated to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty

6. TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Nidek Multi Color Laser Photocoagulator Model MC-300 and the predicate devices has been performed, and the results of this comparison demonstrate that the Nidek Multi Color Laser Photocoagulator Model MC-300 has the same basic technological characteristics as the predicate devices and is equivalent to the marketed predicate devices. The

differences between the Nidek Multi Color Laser Photocoagulator Model MC-300 and the predicate devices are insignificant and do not affect the safety or effectiveness of the device.

7. PERFORMANCE DATA

The Nidek Multi Color Laser Photocoagulator Model MC-300 has been designed and will be tested in accordance with applicable safety standards. System and component testing was completed based on product specifications and hazard effects determined from the risk analysis.

8. CONCLUSIONS

Nidek Incorporated has demonstrated through its evaluation of the Nidek Multi Color Laser Photocoagulator Model MC-300 that the device is equivalent to the predicate device with respect to intended use, technological characteristics, and safety and effectiveness.

Name of Manufacturer: Nidek Co., LTD

Laser Model Name and Number: Nidek Multi Color Laser Photocoagulator Model MC-300

Laser Type: (Circle all that apply)
Alexandrite, Argon, CO2, Copper-Vapor, Diode, Dye, Nd:YAG, Erbium, Hol: YAG, Krypton, Ruby, KTP/532, Excimer, HENE, Accessory, Other pumped solid state

Indications in this application: Ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty

FDA Document Control Number: K042785

FDA Product Codes: 79GEX, 86HQF

Reviewer Computer Initials: ABC

Date of Clearance Letter: 12/3/04

Basis of Approval: (Circle all that apply)
Predicate Device (PD), Clinical Data (CD), Animal Data (AD), Specifications (SPECS), Bench Test Data (BTD), Historical Information (HI), Other _____

Description of Laser: The Nidek Multi Color Laser Photocoagulator Model MC-300 is an ophthalmic photocoagulation system that uses a diode pumped solid state laser beam with wavelengths of 532 nm (green), 561 nm (yellow) and 659 nm (red) for therapeutic treatment as well as the aiming beams. The system can be used in ophthalmic surgical procedures such as retinal and macular photocoagulation, iridotomy and laser trabeculoplasty. The system can be applied to transpupillary photocoagulation procedures using two types of slit-lamp delivery units. The Binocular Indirect Ophthalmoscope (B.I.O.) Delivery Unit allows the physician to perform laser photocoagulation while observing the fundus with the indirect ophthalmoscope.

Operation Modes: (Circle all that apply)
CW, Pulsed, Q-Switched, Mode Locked, Contact, Free Beam, Other _____

Wavelength in Nanometers: 532, 561 and 659

Power/Energy Range (Watts/Joules): 50-2000 mW *

Pulse Width: 0.02-3.00 sec

Repetition Rate: 0.2-1.0 sec in 0.1 sec increments

Delivery System: fiber optic

Comments: * A predicate device for the Nidek GYC-1000 (K030285) is the Nidek GYC-2000 (Model II) (K980547) with a power output of 50-2000 mW in 10 mW increments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2004

Nidek, Incorporated
c/o Ms. Carol Patterson
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, California 92630

Re: K042785
Trade/Device Name: Nidek Multi Color Laser Photocoagulator Model MC-300
Regulation Number: 21 CFR 878.4810, 21 CFR 886.4390
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology; Ophthalmic laser
Regulatory Class: II
Product Code: GEX, HQF
Dated: September 30, 2004
Received: October 6, 2004

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K042785 (To Be Assigned By FDA)

Device Trade Name: Nidek Multi Color Laser Photocoagulator Model MC-300

Indications For Use: The Nidek Multi Color Laser Photocoagulator Model MC-300 is indicated to be used in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

[redacted]

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09/30/04